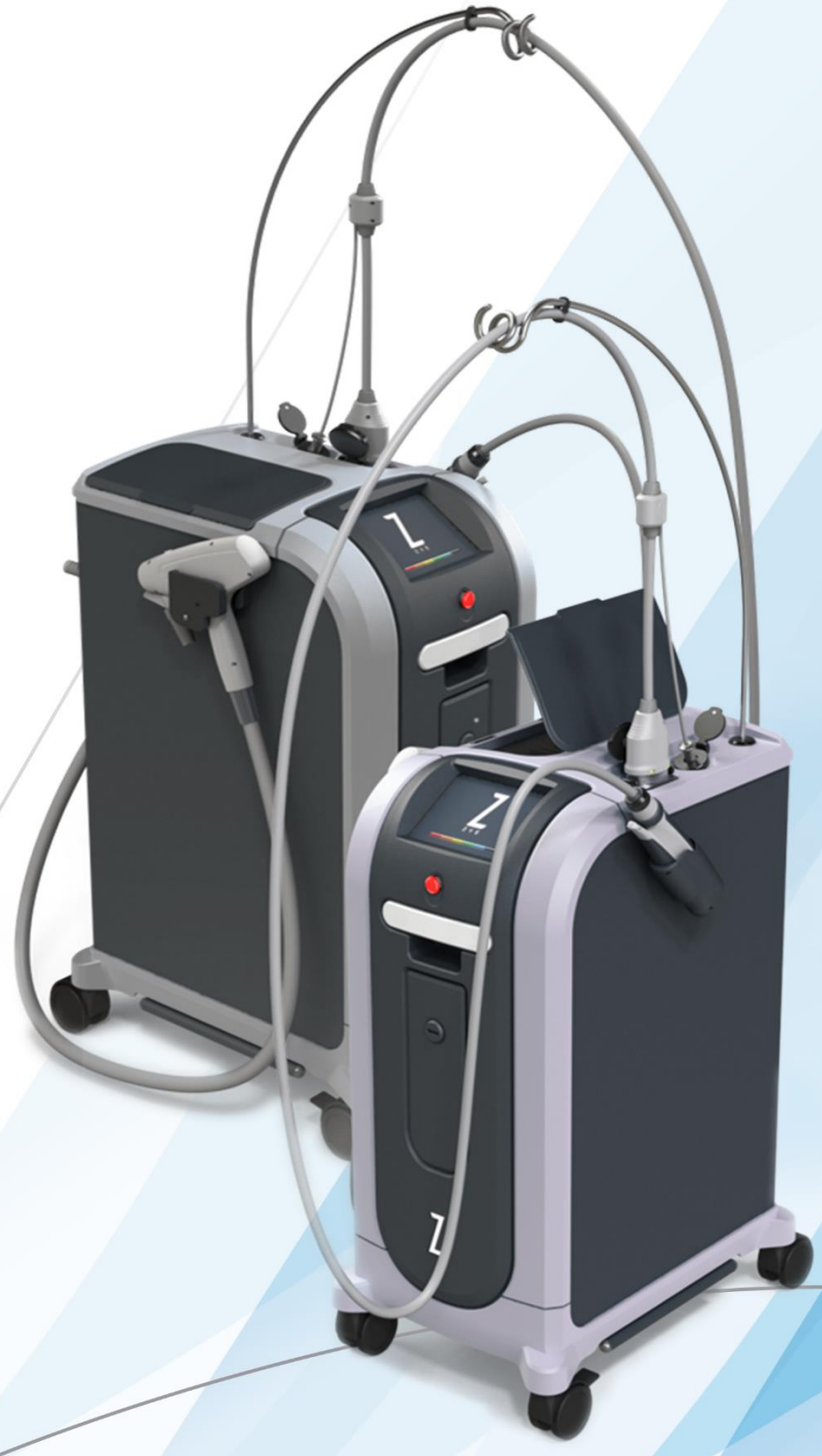
vydence medical

CLINICAL REFERENCE GUIDE

ZYE YAG®

REVIEW 1.2 | NOVEMBER 2020



IMPORTANT NOTICES

- The practical training offered by the company is fundamental for understanding the device and technique. However, this does not replace any other medical qualifications required for its correct use.
- The user manual must be read prior to handling and/or operating the device.
- The ZYE® device and its respective light and LASER handpieces, as well as any accompanying accessories, must be operated by qualified professionals only who are skilled in the techniques required for their use. User qualifications as well as installation and support requirements for performing procedures vary from country to country, so this professional is responsible for consulting with local regulatory agencies.
- This document is not intended to become a complete and absolute guide on using the techniques incorporated in the device and offered in response to the referenced indications. It is understood that the operator of the device in question has all training and qualifications required to properly conduct the surgical procedures proposed in this manual.
- The parameters suggested here are not absolute in clinical practice. Operators must understand treatment interactions with the target tissue and be guided by their clinical experience and professional judgment.
- A detailed and easily adaptable pre-treatment questionnaire is recommended, including patient guidance and highlighting the expected pre- and post-treatment effects, as well as medical history forms, an informed consent form regarding the procedure and any other documents that may be considered essential to the proper execution of the procedure and its respective legal basis. For illustrative and purely exemplary purposes, VYDENCE® has provided templates of these forms together with this manual.

- Always create photographic documentation for all treatment stages. Talk to your patient and explain all the risks involved in the procedure as well as the potential outcomes and its limitations.
- Carefully observe the recommendations listed in the PRECAUTIONS, CONTRAINDICATIONS and SIDE EFFECTS items.
- ZYE® is an electromedical device that may pose a safety hazard to the operator and/or patient under certain circumstances, especially in the event of improper installation, use, operation, and maintenance.
- Safety goggles must be worn by all persons present in the procedure room while it is underway. Never wear safety goggles that do not meet the requirements specified by the manufacturer. Also, even when wearing the proper goggles, never look directly into the emitted light beam.
- Always check the integrity and cleanliness of the spot lenses prior to performing each procedure. Never use the spot if the lens shows any apparent damage. If cleaning is required, follow the procedure as outlined in the product's Instruction Manual.
- The LASER Nd: YAG 1064 must be handled with extreme care with regard to accidental eye exposure. This wavelength has high penetration and a focal length of up to 40 km. The potential risk of permanent eye damage is extremely high. ALL PEOPLE PRESENT IN THE PROCEDURE ROOM MUST USE THE PROPER SAFETY GOGGLES.
- Never use the LASER in places with reflective surfaces due to the risk of accidental eye exposure from the beam.

In addition to being fully compatible with the ETHEREA-MX® handpieces, ZYE® bring tangible improvements to the IPL-Sq®, LongPulse® and DualMode® handpieces. New features are introduced here in this Clinical Reference Guide, as they are only available on the ZYE® platform. The other treatment parameters remain unchanged and are not included here.

WHENEVER THE LASER IS NOT IN USE, proper protection of the beam output is of utmost importance – either with its nozzle or with the protective cap. The procedure in question prevents solid particles from entering the LASER cavity, which in practice may result in permanent damage to the product.

1 USE INDICATIONS

ZYE® incorporates different LASER technologies that offer treatment options indicated for a healthy patient population ranging from 18 to 60 years of age.

ZYE YAG® is indicated for the coagulation and hemostasis of vascular and epidermal tissue lesions, including the treatment of telangiectasias, superficial varicosities, angiomas and spider angiomas, hemangiomas, rosacea and nevus. It is also indicated for non-ablative treatment of facial wrinkles and stretch marks and gradual or permanent removal of unwanted hair, especially in high phototypes (Fitzpatrick V-VI). In the short pulse mode (DYNAMICS®), general treatment indications include: thermal peeling (for reducing fine lines, improving skin texture, pore reduction, rosacea control) and onychomycosis treatment. In the continuous LASER beam delivery mode (INTENSE®), ZYE YAG® is indicated for skin tightening (LASER tightening) in the face, neck (including the jowl) and body (especially the arms, abdomen and chest), as well as reducing fine lines and wrinkles through induction to neocollagenesis by subdermal heating.

2 CLINICAL SAFETY

CONTRAINDICATIONS TO TREATMENT

This equipment is indicated for use in the healthy population from adolescence, but as in many procedures, there are certain clinical conditions not suitable for treatment. They are as follows:

- Tanned skin;
- Active herpes;
- Open and undiagnosed wounds;
- Allergy to sunlight;
- Anticoagulants;
- Malignant injuries;
- Pregnancy;
- Photosensitizing medicines, such as: Tretinoin and estrogen;
- Diabetes, unless it is under control;
- History of keloid scars;
- Hormonal disorders, unless under control;
- pilepsy;
- History of coagulopathic haemorrhages;
- Area with previous treatments with fillers that cannot be fully reabsorbed;
- Active infectious processes.

PRECAUTIONS

- LASERS must be handled with extreme caution to prevent accidental ocular exposure. This wavelength has a high penetrability and carries the risk of potential permanent ocular lesions. Make sure that all people that

could be exposed during treatment are using the correct protection glasses.

- Do not treat vascular lesions through pigmented or tattoo lesions. Hair covering the lesion must also be removed before treatment.
- Always evaluate the photo types: photo types IV and V are at the greatest risk for post-treatment hyperpigmentation. The use of external cooling and greater pulse times can temper this occurrence.
- Cooling before, during, and after treatment is highly recommended. We recommend using cold air coolers such as SIBERIAN-FIT® equipment.
- A thin layer of cool gel can also be used to protect the epidermis during application.
- Do not press the vessels with the application tip for application. Draining them removes the targeted chromophore decreasing the treatment efficacy.
- Wait a few minutes after a shot sequence. Results are delayed especially for darker skin.
- Double shots or “stacked” shots are not recommended for this type of LASER. The risk of ulcers is high.
- Ensure that there are no reflective surfaces in the application room.
- The Nd: YAG LASER has a high penetrability. When performing oral treatments, it is recommended that you provide protection between the teeth and lips to avoid dental discomfort.
- Always check the integrity and cleanliness of the tip lenses before each treatment. Never use them if they appear bolted or cracked. If cleaning is needed proceed according to this manual’s instructions.
- If there are any questions on the parameters of usage, test on a small area for evaluation. Choose a less exposed area. For I-III photo types, wait fifteen to 30 minutes for evaluation. IV-V photo types should wait at least 24 hours.

SPECIFIC PRECAUTIONS FOR IPL-Sq®

- The use of waxes or depilatory creams, tweezers, suntan lotions, is not suggested during the two weeks prior to and after treatment.

- Correctly analyze the area to be treated, checking if the skin has no damage. Assess your skin type and tanning level. In case of unhealed wounds or tan, delay treatment until the problem is resolved.
- Direct sun exposure should be avoided at least 4 weeks prior to application and throughout treatment. Previous sun exposure, even with clothing, should be observed to avoid complications. These cases can cause dyschromia of difficult resolution.
- The patient should use sunscreen in the treated areas, before, during and after the entire treatment.
- Both operator and patient should wear protective eyewear. If the treatment is in the periocular region, always wear goggles that completely block the light.
- Try not to have reflective surfaces in the application room.
- Always clean the sapphire tips with gauze before each procedure. The presence of dirt on the surface can cause points of heat concentration and be harmful to the treatment, and may even cause hypo or hyperchromias.
- The same cleaning care should be applied to the filters. If there is any dirt on your surfaces, heat concentration points can be generated and this will hamper the coating of the cutting filters.
- When in doubt about which parameter to use, make a small test area for evaluation. Choose the least exposed place for this. For I-III skin phototypes, wait 15 to 30 minutes for evaluation. Phototypes IV - V is interesting to wait, at least 24 hours.
- Whenever more energy is needed, the user can increase flow, reduce pulse time, reduce tip cooling or, in the final instance, decrease the cut filter in case of fine hairs. These variations should be performed after the equipment and technical mastery.

POTENTIAL SIDE EFFECTS

The most common side effects described in the literature are:

- Feeling of burning in the area;
- Erythema;

- Edema;
- Hypo or hyperpigmentation;
- Burns;
- Purple;
- Ulcers;
- Thrombophlebitis.
- We also stressed the risk of eye damage due to accidental therapeutic light exposure. For this reason, both the patient and the operator must wear goggles during the entire treatment.
- After treatment, most patients will experience a slight sunburn sensation, which typically disappears without treatment within 2-3 hours.
- Other side effects occur only when the technique is not applied correctly. Among these, the most common is hypopigmentation or hyperpigmentation, which in most cases resolve around 6 months, but that should be treated and monitored. However, in some cases, especially in the case of hypopigmentations, the change in skin color may be permanent.

ADVERSE EFFECTS

As with most LASER procedures, there is an intrinsic risk of incidence of mild to severe side effects, including:

- infections;
- scars or difficulty in healing;
- keloid formation;
- tissue ulceration and/or burns;
- tissue necrosis;
- complications related to anesthetic administration.

3 GENERAL CLINICAL REFERENCE GUIDE

The parameters proposed here are not an absolute guide to clinical practice. Operators must rely on their own clinical experience and professional judgment to perform any treatment proposed in this document.

Handpiece 3-24/HR spots have an optical protection window, which is used to protect the internal lenses during LASER use, preventing the burning of the optical elements due to the entry of dirt or suspended particles during use. Follow the replacement and/or cleaning guidelines set forth in the product Instruction Manual.

ZYE YAG®

ZYE YAG® introduces innovative versatility and technology in expandable platform systems by featuring a unique and dedicated Nd:YAG LASER cavity at 1064 nm, offering practitioners the world's gold standard wavelength for the treatment of a wide variety of vascular lesions (face and lower limbs), LASER rejuvenation and thermal peeling for all phototypes and tanning states, progressive removal for black skin, as well as clinical indication for the treatment of onychomycosis and the new INTENSE® mode (continuous LASER) for localized fat and skin tightening (LASER tightening) on the body and neck. ZYE YAG® offers all the versatility and safety of the 1,064 nm Nd:YAG LASER with much more power and comfort, adding superior results much faster and taking medical practice to a higher level.

VASCULAR LESIONS

Learn about the latest and most acclaimed technology for noninvasive removal of deep and superficial vascular lesions of the face and lower limbs. The LONGPULSE® mode adds the perfect synergy between wavelength, energy density and pulse time, ensuring the safety and complete satisfaction of treatment outcomes.

Benign vascular lesions are much more common than is often thought and affect adult men and women, usually appearing as birthmarks or simply occurring throughout life due to the natural aging process. There are several types of benign vascular lesions and most of them may be easily treated using modern technologies such as the various types of LASERs and IPL devices, which offer a safe, effective and non-invasive alternative for this type of procedure.

The use of LASER technology is always the most recommended for the treatment of lower limb vascular lesions, where vascularization tends to follow deep and superficial flows, which demands a versatile, safe and effective therapeutic option.

VASCULAR LESIONS OF THE LOWER LIMBS

Treatment areas and specificities:

- medial or lateral thigh: easy to treat and only slightly painful;
- ankles: good results, but painful;
- shin: painful region;
- calf: it is well tolerated;
- back of the knees: very sensitive region;
- Make sure the handpiece is properly attached to the ZYE® with the platform already in operation.
- Clean the treatment area with appropriate makeup remover or mild soap to remove any remnants of loose hair or even perfume, deodorant, sunscreen, among others.
- Place the exam table in the Trendelenburg position.

- The use of external cooling prior to the start of the treatment session, with ice packs or topical anesthetics, causes local vasoconstriction and is discouraged at the risk of obtaining ineffective results. This procedure should be performed only after LASER application, in order to assist in collapsing the treated vessel and thus the clinical efficacy.
- Proceed with treatment from distal to proximal vessels, ALWAYS starting with the longest and largest vessels.
- Treatment of smaller vessels should only be initiated when the nourishing vessels are collapsed and closed. This will prevent recurrence. Proceed with the treatment always following the irrigation flow of the larger vessels towards the smaller ones.
- It is important that the vessels are not pressed before and during shots. Simply touch the handpiece over them. This prevents blood dispersion (hemoglobin), which in practice may result in the total or partial reduction of the light's clinical efficacy.
- Vasoconstriction or the immediate disappearance of the treated vessel is the expected reaction to the treatment, most commonly applicable in vessels of a reddish tone. In larger vessels, the expected reaction is darkening due to the coagulation effect (edema/erythema along the vessel). The marginal walls will have a less defined appearance. The vessel may present small spasms resulting from the application of the LASER beam.
- Even if successful, treatment may certainly cause adverse effects on the epidermis – usually mild edema and erythema. Reduce fluence if this occurs. Increase the pulse time if a purple-colored vessel spasm occurs.
- Always start treatment with higher pulse times. This procedure ensures safety due to the controlled action on the epidermis, with reports of lower occurrence of purpura formation, thrombosis and hyperpigmentation.
- Prior analysis by a specialist is of fundamental importance for effective vessel treatment. DOPPLER examination is critical to rule out reflux. The feasibility of successful treatment and its association with other known techniques such as sclerotherapy, intravenous LASER or even surgery/minisurgery must always be analyzed.

- Perform a maximum of 2 applications 1-2 minutes apart. Be careful when trying to solve the problem in a single session – the vessel does not disappear immediately. Successful treatment only depends on the change in vessel color.
- Use long treatment intervals between sessions – about 30 to 40 days. When LASER is used as the sole therapeutic option, the best results usually appear after 3-4 sessions on average. It is possible to combine sclerotherapy to further improve the results obtained.

VASCULAR LESIONS OF THE LOWER LIMBS 3-10/VL ◦ 3-24/HR				
DIAMETER OF THE VESSEL	**SPOT**	**MODE**	**PULSE WIDTH**	**FLUENCE**
0.5 to 1.0 mm	3 mm	LONGPULSE®	10-20 ms	100-300 J/cm²
up to 1.0 mm*	3 mm	LONGPULSE®	15-20 ms	125-250 J/cm²
up to 1.0 mm**	3 or 5 mm	LONGPULSE®	20-30 ms	125-175 J/cm²
1.5 to 2.0 mm	5 or 6 mm	LONGPULSE®	30-40 ms	70-120 J/cm²
2.1 to 4.0 mm	5, 6 or 8 mm	LONGPULSE®	30-60 ms	80-140 J/cm²

*for telangiectasias; **for venulectasias; ***use sapphire cooling of the 3-10/VL handpiece at the maximum level and use guide LASER intensity control for thinner veins and vessels; the 3-24/HR handpiece requires the use of external cooling.

VASCULAR LESIONS OF THE FACE

- Always use the 3 mm spot to treat vessels in the nasal wing region with simultaneous external cooling. The absence of cooling or the use of larger spots, such as 6 mm, may increase the risk of burns and undesired tissue retraction. Remember to always use the spot perpendicular to the treatment region, with the spacer resting on the tissue. The LASER focus was specially designed to adjust to this distance.
- Smaller spots usually require the use of higher fluence values when compared to larger spots. On the other hand, it is not a fact that this results in more aggressive treatments, since the energy delivered per shot is usually lower.

VASCULAR LESIONS OF THE FACE 3-10/VL ◦ 3-24/HR ◦ 5-15/LT					
DIAMETER OF THE VESSEL	SPOT	MODE	PULSE WIDTH	FLUENCE	FREQUENCY
up to 0.5 mm	3 mm	LONGPULSE®	10 ms	100-200 J/cm²	1-2 Hz
0.5 to 1.0 mm	3 mm	LONGPULSE®	10-20 ms	150-275 J/cm²	1-2 Hz
up to 1.0 mm	3 mm	LONGPULSE®	15-20 ms	100-150 J/cm²	1-2 Hz
up to 1.0 mm	3, 5 or 6 mm	DYNAMICS®	650 us	20-50 J/cm²	5-10 Hz
up to 0.5 mm	3 mm	DYNAMICS®	650 us	10-50 J/cm²	5-10 Hz

*use sapphire cooling of the 3-10/VL handpiece at the maximum level and use guide LASER intensity control for thinner veins and vessels; the 3-24/HR handpiece requires the use of external cooling;

NEVUS RUBI

- The number of sessions can vary from 1 to 4 depending on the size and number of lesions, with an average interval of 30 days;

NEVUS RUBI 3-10/VL ◦ 3-24/HR			
SPOT	MODE	PULSE WIDTH	FLUENCE
3 mm	LONGPULSE®	20-30 ms	100-150 J/cm²

*use sapphire cooling of the 3-10/VL handpiece at the maximum level and use guide LASER intensity control for thinner veins and vessels; the 3-24/HR handpiece requires the use of external cooling;

FACIAL WRINKLES

The proposal for the treatment of facial wrinkles has always been a major concern for doctors and patients around the world, especially with specific regard to collagen stimulation. Traditional rejuvenation is a medical-aesthetic procedure that seeks to smooth tissue irregularities to stimulate skin cell renewal, mainly with the support of technology.

Rejuvenation through the use and incorporation of LASER light sources treats specific skin conditions such as wrinkles, scars and fine lines. The main rejuvenation action mechanism in these cases is the creation of thermal tissue

damage, which promotes the creation of healthy new cells and stimulates the regeneration of collagen and elastin fibers. Nowadays, with the advent and constant incorporation of new LASER technologies, rejuvenation also encompasses fractional resurfacing and fractional photorejuvenation procedures.

- Make sure the handpiece is properly attached to the ZYE® with the platform already in operation.
- Clean the treatment area with appropriate makeup remover or mild soap to remove any remnants of loose hair or even perfume, deodorant, sunscreen, among others.
- Clinical literature reports the use of the Nd:YAG LASER at 1064 nm on wrinkles and stretch marks. Apply across the entire tissue area to be treated. When applied, in order to improve the effect of light scattering and superficialization, the most common reports are of use at a 45° inclination angle, given the depth of the Nd:YAG LASER beam's action at 1064 nm.
- To ensure the safety of the procedure, use the spacer as a reference for the distance between shots (about 1/2 of the total spot size; ~3 mm).

FACIAL WRINKLES 3-10/VL ◦ 3-24/HR ◦ 8-18/HR					
TREATMENT	**SPOT**	**MODE**	**PULSE WIDTH**	**FLUENCE**	**PASSES**
Fine lines and wrinkles	6, 8 or 10 mm	LONGPULSE®	100 ms	40-60 J/cm²	1
Skin toning	6, 8 or 10 mm	LONGPULSE®	60-100 ms	30-50 J/cm²	1

*use the handpieces with cooling (by air, through an external cooler, or by the sapphire window); note that the larger the spot, the better the treatment coverage area, but the greater the risk of adverse effects due to the use of excessive energy or pulse time.

PERMANENT HAIR REDUCTION

Permanent hair reduction using technology was first done around 20 years ago, and became available for commercial use in the mid-90s. Using melanin as the target chromophore of the treatment, with specific wavelengths and

parameters, LASER epilation has become one of the most widespread medical aesthetic procedures in clinics and medical centers worldwide, keeping at the forefront of traditional hair removal methods.

The efficacy of epilation is now accepted by common agreement in dermatology, especially regarding the duration of treatment, safety with respect to higher phototypes, and especially the speed of the results obtained. Numerous trials and published studies prove the clinical efficacy of the procedure.

- Make sure the handpiece is properly attached to the ZYE® with the platform already in operation.
- Clean the treatment area with appropriate makeup remover or mild soap to remove any remnants of loose hair or even perfume, deodorant, sunscreen, among others.
- To prepare for the treatment, it is recommended that the patient use a razor blade to shave the hair. This preparation should be performed right before application.
- When using the 3-24/HR® handpiece, the use of external cooling prior to the start of the treatment session, including ice packs, is ALWAYS a recommendation due to the need for epidermal protection, improved patient comfort and the respective therapeutic yield of the procedure.
- Increased fluence may be a factor in improving the response to treatment efficacy. On the other hand, some specific factors – phototype, tanning, density and location of the hair – may require limitation of the parameterized value given the risk of adverse effects on the treatment. Always perform a test shot in a less visible region to monitor the progression of results and possible adversities.
- The high penetration of the Nd:YAG LASER beam at 1064 nm may result in lesions to adjacent tissues, especially in the mouth region, due to the thickness of the nearby skin. The use of a protector between the teeth and lips is always recommended when performing treatments in this region. Care must also be taken over regions of bone superficialization, given the risk of ulcers and burns.
- Proceed with application of the LASER in the target region, using only a few shots. Wait a few minutes and check the effects on the tissue. For

PHOTOTYPES I-III, wait at least 15 minutes. For PHOTOTYPES IV-VI, 24 hours. Reactions considered normal, which are immediate to treatment, can include mild erythema of the skin, singed skin with a characteristic odor, and perifollicular edema. On the other hand, the absence of such effects does not imply ineffectiveness of the previously adjusted parameters.

- If there is no noticeable change in the appearance of the follicles, increase fluence value at regular increments. Note the correlation of the resulting adverse effects.
- In case of severe edema, apply soothing lotion and reduce fluence or increase pulse time. Topical anesthetic may be used for patients with skin more sensitive to pain.
- Move the handpiece over the area adjacent to the previously treated area and continue treatment of the entire area. Overlapping shots may occur normally as long as the patient's skin is not sensitized to the treatment.
- The number of treatment sessions ranges from 4 to 8. Areas with lighter and finer hair, hormonal changes or even sites less accessible for treatment (upper lip, chin) may induce a relative increase in the scheduled number of sessions.
- The time gap between sessions may vary from 30-60 days. Always re-examine the patient every 30 days. Prioritize reapplication of the procedure whenever new hair grows in the region. As of the second session, it is possible to increase the interim period between sessions to wait for new hair growth in the treatment region. This growth cycle may vary depending on gender, age, hormonal activity, among others.
- The time for hair removal from the treated area occurs 10 to 15 days after the session.
- Once treatment is complete, clean the treated area to remove residues resulting from the hair follicle combustion.
- Applying ice packs and/or cold compresses is always beneficial to relieve the burning sensation immediately following treatment. After a few minutes, dry the treated area, apply soothing lotion and sunscreen.

PERMANENT HAIR REDUCTION 3-24/HR						
SKIN TYPE	HAIR TYPE		SPOT	MODE	PULSE WIDTH	FLUENCE
	COLOR	THICKNESS				
I and II	black	thin / thick	6 mm 10 mm 14 mm 18 mm 20 mm 24 mm	LONGPULSE®	20-30 ms	45-60 J/cm^2 30-40 J/cm^2 24-30 J/cm^2 14-20 J/cm^2 12-18 J/cm^2 10-16 J/cm^2
III			6 mm 10 mm 14 mm 18 mm 20 mm 24 mm	LONGPULSE®	20-30 ms	45-55 J/cm^2 25-35 J/cm^2 20-26 J/cm^2 12-16 J/cm^2 10-14 J/cm^2 8-14J/cm^2
IV			6 mm 10 mm 14 mm 18 mm 20 mm 24 mm	LONGPULSE®	30-40 ms	40-55 J/cm^2 25-30 J/cm^2 20-24 J/cm^2 10-14 J/cm^2 8-14 J/cm^2 8-12 J/cm^2
V			6 mm 10 mm 14 mm 18 mm 20 mm 24 mm	LONGPULSE®	40 ms	40-50 J/cm^2 25-30 J/cm^2 20-24 J/cm^2 10-14 J/cm^2 6-12 J/cm^2 6-10 J/cm^2
VI			6 mm 10 mm 14 mm 18 mm 20 mm 24 mm	LONGPULSE®	40-50 ms	40-50 J/cm^2 20-30 J/cm^2 16-24 J/cm^2 8-14 J/cm^2 4-10 J/cm^2 2-8 J/cm^2

*use the handpieces with cooling (by air, through an external cooler, or by the sapphire window); achieve end point for permanent hair reduction, such as perifollicular edema and / or mild erythema.

PERMANENT HAIR REDUCTION 3-10/VL						
SKIN TYPE	HAIR TYPE		SPOT	MODE	PULSE WIDTH	FLUENCE
	COLOR	THICKNESS				
I and II	black	thin / thick	6 mm 8 mm 10 mm	LONGPULSE®	20-30 ms	50-70 J/cm^2 35-50 J/cm^2 20-35 J/cm^2
III			6 mm 8 mm 10 mm	LONGPULSE®	20-30 ms	45-50 J/cm^2 30-45 J/cm^2 25-35 J/cm^2
IV			6 mm 8 mm 10 mm	LONGPULSE®	30-40 ms	35-40 J/cm^2 25-35 J/cm^2 20-30 J/cm^2
V			6 mm 8 mm 10 mm	LONGPULSE®	40 ms	35-40 J/cm^2 30-35 J/cm^2 20-30 J/cm^2
VI			6 mm 8 mm 10 mm	LONGPULSE®	40-50 ms	30-35 J/cm^2 25-30 J/cm^2 24-30 J/cm^2

*use the handpieces with cooling (by air, through an external cooler, or by the sapphire window); achieve end point for permanent hair reduction, such as perifollicular edema and / or mild erythema

PERMANENT HAIR REDUCTION 8-18/HR						
SKIN TYPE	HAIR TYPE		SPOT	MODE	PULSE WIDTH	FLUENCE
	COLOR	THICKNESS				
I and II	black	thin / thick	8 mm 10 mm 12 mm 14 mm 16 mm 18 mm	LONGPULSE®	20-30 ms	35-45 J/cm² 30-40 J/cm² 26-30 J/cm² 24-30 J/cm² 18-20 J/cm² 14-20 J/cm²
			08 mm 10 mm 12 mm 14 mm 16 mm 18 mm	LONGPULSE®	20-30 ms	45-50 J/cm² 25-35 J/cm² 24-30 J/cm² 20-26 J/cm² 16-20 J/cm² 12-16 J/cm²
IV			8 mm 10 mm 12 mm 14 mm 16 mm 18 mm	LONGPULSE®	30-40 ms	35-40 J/cm² 25-30 J/cm² 22-28 J/cm² 20-26 J/cm² 14-29 J/cm² 10-14 J/cm²
V and VI			8 mm 10 mm 12 mm 14 mm 16 mm 18 mm	LONGPULSE®	40-50 ms	30-40 J/cm² 20-30 J/cm² 20-26 J/cm² 20-24 J/cm² 12-16 J/cm² 10-14 J/cm²

*use the handpieces with cooling (by air, through an external cooler, or by the sapphire window); achieve end point for permanent hair reduction, such as perifollicular edema and / or mild erythema.

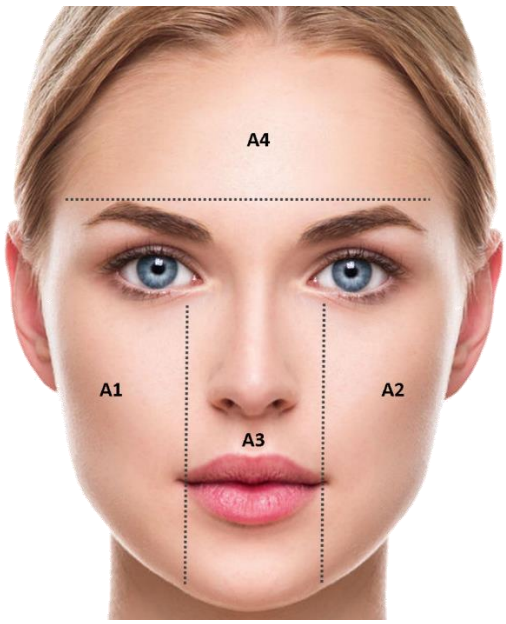
LASER THERMAL PEELING

The DYNAMICS® technology incorporated into the ZYE® 5-15/LT®, 3-10/VL® or 3-24/HR® handpieces considerably broadens the range of clinical and aesthetic applications of the clinic. The DYNAMICS® operating mode offers a unique range of benefits to patients, adding total safety and effectiveness of results.

The DYNAMICS® operating mode works with extremely short pulse times (up to 1 ms), seeking to produce heat by accumulating shots. General treatment indications include: thermal peeling (for reducing fine lines, improving skin texture, pore reduction, rosacea control) and onychomycosis treatment.

It is achieved by applying the DYNAMICS® mode to promote skin revitalization, improve the flushing effect of rosacea, as well as pore closure. Totally painless, this treatment can be performed any time of the year and on any phototype.

- Clean the treatment area with appropriate makeup remover or mild soap to remove any remnants of loose hair or even perfume, deodorant, sunscreen, among others.
- For thermal peeling, which encompasses general rejuvenation indications, the suggestion is to accumulate 500 to 1.000 shots per treatment region, sectioning the face into: right cheekbone, left cheekbone, forehead and T-zone (nose, upper lip and chin);
- Heating control should follow patient's report (with the aid of a thermometer). Therefore, the use of topical anesthetic and/or cooling is not recommended.
- If the patient reports too much heat, shot frequency should be reduced before reducing fluence – first from 10 to 7 Hz and then from 7 to 5 or 3 Hz.
- The number of treatment sessions ranges from 1 to 8, depending on the overall goal.



THERMAL PEELING 3-10/VL ◦ 3-24/HR ◦ 5-15/LT						
INDICATION	**SPOT**	**MODE**	**PULSE WIDTH**	**FLUENCE**	**REP. RATE**	**SHOTS**
Rosacea control	3 or 5 mm	DYNAMICS®	200 or 300 µs	10-40 J/cm²	3-10 Hz	500-1000/ Quadrant
Texture and pores	5, 6, 8 or 10 mm	DYNAMICS®	650 µs	8-20 J/cm²	3-10 Hz	500-1000/ Quadrant

ONYCHOMYCOSIS

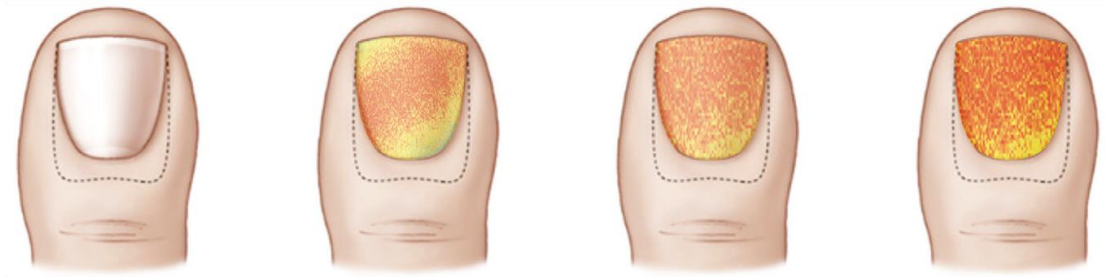
Onychomycosis is an infection of the nails, especially the toes, caused by fungi that feed on keratin. The constant use of closed-toe shoes creates moist, dark and warm environments, favoring the growth of these fungi.

Conventional treatments range from the local use of creams, solutions or polishes to oral forms (long lasting – on average 6 months, but can reach 1 year).

The use of the LASER emerges as a therapeutic option, aiming to heat the site, reduce and/or treat the pathology.

- Remove residue of nail polish and/or creams (be very careful with darker nail polish!).
- For best use of the light, nails should be buffed prior to treatment.
- For onychomycosis, the ideal is to accumulate between 600 and 800 shots on the affected nails or until reaches a temperature of 42ºC, following the application pattern indicated in the following image. It is worth remembering that the goal of onychomycosis treatment via LASER is to induce uniform and homogeneous heating of the nail.
- The most tolerable way for the patient is to perform intermittent cycles of 100-150 hallux shots and 25 to 30 shots on the other affected nails, repeating this same procedure 5 times to reach the recommended total number of shots.
- Heating control should follow patient's report (with the aid of a thermometer). Therefore, the use of topical anesthetic and/or cooling is not recommended.
- The number of treatment sessions ranges from 2 to 8.

- The treatment interval between sessions may vary from 30-45 days. They may be combined with topical treatments to enhance results.



ONYCHOMYCOSIS 3-10/VL ◦ 3-24/HR ◦ 5-15/LT					
SPOT	**MODE**	**PULSE WIDTH**	**FLUENCE**	**REP RATE**	**SHOTS**
3 mm	DYNAMICS®	300 µs	10-40 J/cm²	3-10 Hz	300-600
5 mm	DYNAMICS®	300 µs	10-12 J/cm²	3-10 Hz	until reaching 42ºC
5 mm	LONGPULSE®	40 ms	40-80 J/cm²	1 Hz	until reaching 42ºC

*use the handpieces with cooling (by air, through an external cooler, or by the sapphire window) and insert the cooler between the passes; note that the larger the spot, the better the treatment coverage area, but the greater the risk of adverse effects due to the use of excessive energy or pulse time.

LASER TIGHTENING

Noninvasive treatment of flaccidity in the face and body is one of the most sought after treatments in clinics and doctors' offices around the world. With the advent of new LASER and light technologies, the procedure has been producing increasingly better and safe results, being indicated for almost all phototypes without general restrictions.

LASER tightening is one of the most modern aesthetic procedures today, acting at the sub-dermal level in the tissue through the specific wavelength capable of treating the deeper layers of the skin, inducing homogeneous and controlled heating from the inside out.

LASER TIGHTENING 5-15/LT					
TREATMENT AREA	**SPOT**	**MODE**	**TIME SHOT**	**POWER**	**TOTAL ENERGY**
Face	10 or 15 mm	INTENSE®	15 s	30-40 W	6 a 7 KJ/ Hemiface
Chest, neck and jowl	10 or 15 mm	INTENSE®	15 s	30-40 W	7 to 10 KJ/ Quadrant
Body	15 mm	INTENSE®	15 s	30-50 W	10 to 14 KJ/ Quadrant

Attention: the temperature of the treated tissue should be increased to 42°C for intense collagen stimulation. After reaching it evenly throughout the quadrant, continue heating for at least 2 minutes.

ZYE YAG®: AFTER TREATMENT

- The use of SPF 60 sunscreen is recommended throughout the treatment for at least 30 days before the first application. The patient should always use sunscreen on the treated areas before, during and after treatment.
- In the case of hair removal or rejuvenation treatments that may damage or sensitize the surface of the skin, it is recommended to avoid using waxes or depilatory creams, tweezers and tanning creams for 2 weeks before and after treatment.
- Soothing lotion applied in circular movements and cold compresses may help to relieve the burning sensation after treatment. After applying and performing the procedure, the treated part should always be gently washed for up to 3 days, avoiding intense friction.
- The use of LED and topical and/or oral corticosteroids to soothe the skin immediately after each session is always recommended.
- Clinical management pre- and post-treatment is critical to the success of the therapy as well as the prevention of adverse and unwanted effects.
- Patients should also be instructed to contact their physician immediately if any signs of infection (pus, itching, oozing or fever), significant pain or complications and side effects appear.

- Patients must be advised not to delay going to a hospital or health facility for immediate urgent care if severe or abnormal side effects occur during post-treatment.
- The patient must return for medical follow-up as prescribed. This is usually 24-72 hours after the procedure.
- For the treatment of vascular lesions, the use of compression dressings immediately after the treatment is recommended, as well as maintaining the legs elevated for the next 24 hours. The use of compression socks for the 5-7 days following the treatment is recommended when the lesions correspond to the treatment of large vessels. Use for 3 weeks in the event of associated sclerosing after the treatment. Avoid hot showers, walks and aerobic activities for 2 weeks (3 days at a minimum).
- Use 18 G needles if clot removal is required.
- In the 2-3 weeks following the treatment, the return of vessels to their previous appearance is not indicative of treatment failure. This transient effect is commonly reported. Improvement usually occurs within the next 6-8 weeks.

4 IPL-Sq® NEW INDICATIONS

The parameters proposed here are not an absolute guide to clinical practice. Operators must rely on their own clinical experience and professional judgment to perform any treatment proposed in this document.

In addition to being fully compatible with the ETHEREA-MX® handpieces, ZYE® bring tangible improvements to the IPL-Sq®, LongPulse® and DualMode® handpieces. New features are introduced here in this Clinical Reference Guide, as they are only available on the ZYE® platform. The other treatment parameters remain unchanged and are not included here.

DYNAMICS® MODE

The DYNAMICS® technology incorporated into the IPL-Sq® handpiece provides a new therapeutic option for ZYE®, which expands the use of broad spectrum handpiece filters now with the in-motion function for the chest, arms and legs in indications for pigmentary lesions, vascular lesions and hair removal. The IPL-Sq® DYNAMICS® mode works at a frequency of 3 Hz, reducing the interval between lamp shots.

IPL-Sq® **DYNAMICS®**					
SKIN TYPE	**PASSES**	**FLUENCE**	**λ**	**PULSE WIDTH**	**COOLING**
I-IV	until erythema*	4-7 J/cm²	Except 390 nm	10 ms	2 °C

*a thin layer of gel may be needed to make passing the handpiece easier.

ACNE VULGARIS

Acne is a disease characterized by increased secretion of sebum by the sebaceous glands. This excess sebum mixes together with dead skin cells that accumulate in the pilosebaceous follicle orifice, leading to clogged pores and causing sebum to accumulate in the affected regions. The accumulation of sebum releases substances that irritate the skin and cause inflammation, in addition to creating an environment conducive to bacterial growth, such as propionibacterium acnes. If not treated properly, acne can lead to scarring.

Acne affects thousands of men and women worldwide. Acne is most common in adolescence, but can affect people of all ages, causing great distress and discomfort, as well as impacting self-esteem.

In addition to topical and oral antibiotics, modern technology provides new treatment options, such as IPL, which has become quite popular in recent years and is known for its safety and effective results.

- Make sure the IPL-Sq® handpiece is properly attached to the ZYE® with the platform already in operation.
- The dual-band filter at 390-510~850-1200 is indicated for direct antibacterial action and attenuation of inflammatory reactions by combining two different cutting filters into one;
- The VASCUTIPS® may be combined with any wavelength. However, the warnings addressed at the beginning of this chapter must be observed.
- Attach the corresponding filters following the instructions in the TABLE below. Press START once the parameters are properly set.

- The device will cool the handpiece and the message screen will display “COOLING TIP”. Once the device and the handpiece are ready for use, a beep will sound and the message will disappear from the screen.
- Position the sapphire tip on top of the area to be treated.
- Make sure the sapphire is perpendicular to the treatment area and press the shot button/pedal.
- Wait a few minutes and check the effects on the tissue. For PHOTOTYPES I-III, wait at least 15 minutes. For PHOTOTYPES IV-VI, 24 hours. Reactions considered typical, immediate to the treatment, may be noticed through mild erythema and edema.
- If there is no noticeable change in the appearance of the tissue, increase fluence value with single increments (1 J/cm^2). Note the correlation of the resulting adverse effects.
- In case of intense edema, apply soothing lotion. Do not use substances that can further damage acne skin and worsen the inflammatory condition.
- Move the handpiece over the area adjacent to the previously treated area and continue treatment of the entire area.
- The number of treatment sessions ranges from 1 for immediate response (pre-event) to 10 for complete attenuation of visible symptoms. On the other hand, treatment maintenance is required. The IPL-Sq® indication is mainly due to the continuous improvement of the pustules. The process begins immediately after treatment and although it does not cure the disease, it reduces its symptoms (blemishes) for a period of 7-14 days. It may and should be indicated whenever a rapid reversal of the symptomatic condition is desired. HOWEVER, IT SHOULD NOT BE SOLD AS A CURE FOR ACNE.
- The treatment interval between sessions may vary from 7-14 days.
- Applying ice packs and/or cold compresses is always beneficial to relieve the burning sensation immediately following treatment. Apply specific products for each case, instructing the patient on the use of medication indicated for the continued treatment of the indication.

ACNE VULGARIS						
SKIN TYPE	LESION TYPE	PASSES	FLUENCE	λ	PULSE WIDTH	COOLING
I-II	Pustular or inflammatory	1-2x	10-16 J/cm²	390 nm	30-40 ms	2 °C
III-IV	Pustular or inflammatory	1-2x	10-14 J/cm²	390 nm	40-60 ms	2 °C
V-VI	Pustular or inflammatory	1-2x	9-12 J/cm²	390 nm	100 ms	2 °C

Associating topical retinoids is critical to the total success of the treatment. IPL-Sq® technology, when used alone, relieves but does not permanently eliminate symptoms and the disease itself;

Sessions should not exceed the 2-week limit;

It is critical that the patient is not tanned for active acne treatment in particular. The 390 nm filter, despite adequate UV protection, has a greater predisposition to induce hyperchromia formation. If hyperchromia occurs in any case, lower energy levels to an acceptable minimum or even discontinue treatment. Greater care must be taken with higher phototypes;

VITILIGO

Vitiligo is a disease characterized by loss of skin color. Lesions are formed due to the decrease or absence of melanocytes (cells responsible for the formation of melanin, the skin's color pigment) at the affected sites. The causes of the disease are not yet clearly established, but autoimmune phenomena appear to be associated with vitiligo. In addition, emotional changes or traumas may be among the factors that trigger or aggravate the disease.

The disease is characterized by hypopigmentation skin lesions, i.e., white spots on the skin with a characteristic distribution. Spot size varies. Several therapeutic options are available for treating vitiligo, which vary according to each patient's clinical condition. The dermatologist is the most qualified professional to diagnose and treat the disease.

Narrow band ultraviolet B (UVB-nb) phototherapy is indicated for almost all forms of vitiligo, with excellent acknowledged results, especially for facial and trunk lesions. Ultraviolet A (PUVA) phototherapy may also be used, as well as technologies such as LASER.

VITILIGO						
SKIN TYPE	LESION TYPE	PASSES	FLUENCE	λ	PULSE WIDTH	COOLING
I-IV	Recent lesions	until erythema*	8-16 J/cm²	390 nm	30-40 ms	2 °C

*achieve minimum desired erythematous dose over the lesion;

PSORIASIS

Psoriasis is a chronic, non-contagious, multigene (several genes involved) inflammatory skin disease, with genetic incidence in about 30% of cases. It is characterized by reddish and scaly lesions, usually in plaques, most commonly on the scalp, elbows and knees. It arises mainly before the age of 30 and after the age of 50, but in 15% of cases may occur during childhood.

Psoriasis has no cure, but there are different types of treatment available (relapse control), depending on the intensity of the disease. Mild and moderate cases (about 80%) can be controlled with local medication, skin hydration, sun exposure and even LASER and/or light treatments (ultraviolet A and B light baths).

PSORIASIS						
SKIN TYPE	LESION TYPE	PASSES	FLUENCE	λ	PULSE WIDTH	COOLING
I-III	No crust	1-2x	10-16 J/cm²	390 nm	30-40 ms	2 °C
III-IV	No crust	1-2x	10-14 J/cm²	390 nm	40-60 ms	2 °C

5 LongPulse® NEW INDICATIONS

The parameters proposed here are not an absolute guide to clinical practice. Operators must rely on their own clinical experience and professional judgment to perform any treatment proposed in this document.

In addition to being fully compatible with the ETHEREA-MX® handpieces, ZYE® bring tangible improvements to the IPL-Sq®, LongPulse® and DualMode® handpieces. New features are introduced here in this Clinical Reference Guide, as they are only available on the ZYE® platform. The other treatment parameters remain unchanged and are not included here.

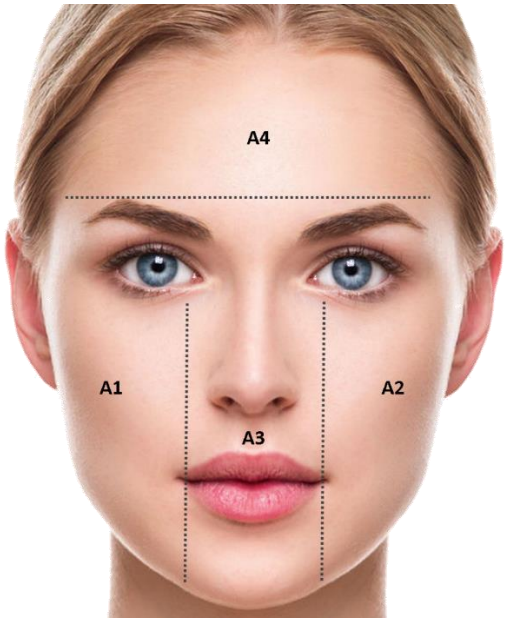
SPIDER VEINS

The Thermal Peeling LASER is delivery of an Nd:YAG LASER in extremely short pulse times (up to 1 ms, in DYNAMICS® mode) to produce heat through the accumulation of shots.

This treatment is totally painless and can be done any time fo the year on any skin type. Its main indications are the reduction of fine lines and pores, improvement of skin texture, rosacea control and the treatment of onychomycosis.

It is also possible to treat spiders veins when the Thermal Peeling LASER is used with the LongPulse® handpiece on the ZYE YAG® platform.

- Clean the treatment area with appropriate makeup remover or mild soap to remove any remnants of loose hair or even perfume, deodorant, sunscreen, among others.
- For thermal peeling, which encompasses general rejuvenation indications, the suggestion is to accumulate 500 to 1.000 shots per treatment region, sectioning the face into: right cheekbone, left cheekbone, forehead and T-zone (nose, upper lip and chin).
- Heating control should follow patient's report (with the aid of a thermometer). Therefore, the use of topical anesthetic and/or cooling is not recommended.
- If the patient reports too much heat, shot frequency should be reduced before reducing fluence – first from 10 to 7 Hz and then from 7 to 5 or 3 Hz.
- The number of treatment sessions ranges from 1 to 8, depending on the overall goal.



SPIDER VEINS				
SPOT	**MODE**	**PULSE WIDTH**	**REP. RATE**	**FLUENCE**
Ø 3 mm	DYNAMICS®	650 µs	3-10 Hz	25-45 J/cm²

6 DualMode® NEW INDICATIONS

The parameters proposed here are not an absolute guide to clinical practice. Operators must rely on their own clinical experience and professional judgment to perform any treatment proposed in this document.

In addition to being fully compatible with the ETHEREA-MX® handpieces, ZYE® bring tangible improvements to the IPL-Sq®, LongPulse® and DualMode® handpieces. New features are introduced here in this Clinical Reference Guide, as they are only available on the ZYE® platform. The other treatment parameters remain unchanged and are not included here.

ERBIUM DYNAMICS®

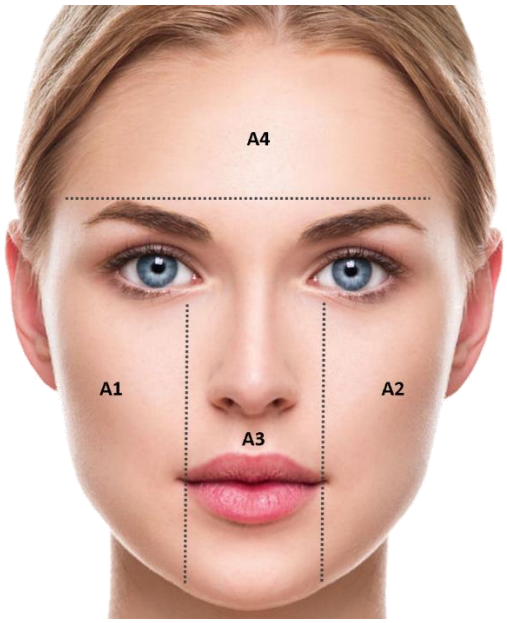
The ERBIUM DYNAMICS® (Er: DYNAMICS®) procedure acts on ablation of the superficial tissue in order to stimulate its regeneration and consequent replacement. The effect is improved skin appearance as well as lightening of the tissue. It is a safe and effective procedure for working with an extremely short pulse.

- Make sure the DualMode® handpiece is properly attached to the ZYE® with the platform already in operation.
- Clean the treatment area with appropriate makeup remover or mild soap to remove any remnants of loose hair or even perfume, deodorant,

sunscreen, among others. The area must be completely dry before treatment begins.

- Even if successful, treatment may cause adverse effects on the epidermis – usually mild edema and erythema. If that is the case, reduce fluence used and decrease the number of shots per area.
- Prophylactic prescription, especially in patients with a history of herpes, is commonly reported in clinical literature. Due to unprotected exposure of the tissue to the environment, risk of fungal and/or bacterial infections is enhanced.
- Post-treatment clinical recommendations should be fully and properly prescribed and strictly followed, as they are important for proper recovery and to avoid the incidence of undesired effects, such as contact dermatitis, for example.
- Perform LASER shots in an area with little or no visible exposure. Wait a few minutes and check the effects on the tissue. For PHOTOTYPES I-III, wait at least 15 minutes. For PHOTOTYPES IV-VI, 24 hours. Reactions considered typical, immediate to the treatment, may be noticed through mild erythema and edema.
- If there is no noticeable change in the appearance of the tissue, increase fluence value at regular increments and increase the number of shots per area. Note the correlation of the resulting adverse effects.
- In case of intense edema or erythema, apply soothing lotion.
- If the patient is still in the first treatment session, or if questions regarding the use of the device arise, choose to use more conservative parameters. Observe the patient's reaction to the shots to match the best parameter for the specified treatment.
- When proceeding with treatment in the periorbital region, use intraocular protection. Using the LASER on the eyelid area without proper protection may result in irreversible vision damage.
- Do not apply the LASER over tattoos or permanent makeup. The procedure should be conducted with extreme caution over the hair and eyebrow regions – if necessary, protect the area in order to ensure greater safety to the procedure.

- Observe immediate tissue reaction as treatment is performed. Pay very close attention to undesired effects.
- It is worth noting the face features thinner tissue areas. In these regions, caution is required when applying more aggressive parameters.
- The ablative treatment follows a specific treatment logic, indicated in the table below. The physical application logic and the interaction of LASER with tissue are of fundamental importance in order to learn the limits and points of treatment optimization, including safety and clinical efficacy of results.
- Treatment with Er:DYNAMICS® can be considered lunch time, i.e. with no downtime, but parameters should be adjusted accordingly.
- The number of shots, in addition to fluence, determines the treatment aggressiveness and consequently the post-treatment (downtime). The recommended average of 1.000 shots per quadrant.



ERBIUM DYNAMICS®					
SPOT	PULSE WIDTH	FLUENCE	REP. RATE	SHOTS	SKIN TYPE
12 mm	200 µs	0,25 -0,55 J/cm^2	10 Hz	1.000/ Quadrant	I-IV

EYELID RESURFACING

Resurfacing of the eyelid region can be done with minimal pain and downtime when performed with the TrueLift® 8 mm spot, exclusive for use with the DualMode® handpiece, on ZYE® platforms.

The TrueLift® 8 mm spot has microprocessor technology to create pulse trains in a single shot of the beam, with a longer total firing time and homogeneous energy delivery. This favors deep heating and collagen stimulation through a coagulative effect while mitigating the ablative effect inherent to the 2940nm Er:YAG LASER (and other similar technologies).

- Make sure the spot is properly attached to the DualMode® handpiece, with the platform already in operation;
- When treatment is performed in the eye area, make sure the patient is wearing the eye protector properly, as exposure of the eyes to the LASER beam may result in permanent vision damage;
- Slide the spot by 1 to 2 cm during a single shot, which avoids excessive heat accumulation in a single point and possible side effects;
- The number of sessions usually ranges from 2 to 5, with a treatment interval of around 20 to 30 days, depending on treatment aggressiveness;
- Average of 10 to 50 shots in each area, respecting the patient's sensitivity. Ideally, use less energy with the highest number of shots to induce heating homogeneity;
- The tip should be cleaned after each use with a patient;
- After the procedure, the patient may notice mild erythema and edema, and small punctiform lesions which should disappear within 1 to 3 days, as with the most superficial LASER peelings.

EYELID RESURFACING					
SPOT	**PULSE WIDTH**	**FLUENCE**	**REP. RATE**	**SHOTS**	**SKIN TYPE**
TrueLift® 8 mm	Smooth pulse	15 -25 mJ/mtz	1 Hz	30-50/ Eyelid	I-IV

7 ZYE XD®

The parameters proposed here are not an absolute guide to clinical practice. Operators must rely on their own clinical experience and professional judgment to perform any treatment proposed in this document.

The treatments proposed herein are a combination of therapeutic options that also include ETHEREA-MX® handpieces. Therefore, prior consultation of the Clinical Reference Guides distributed along with ETHEREA-MX® handpieces is required. The tables associated with ZYE YAG® or ZYE ALX®, proposed herein, also do not excuse the reading of the previous chapters of this document.

OVERALL GUIDELINES

Treatments combined with different wavelengths for different indications are called ZYE XD® treatments. The main idea is to optimize the results obtained using ZYE's unique technologies for the benefit of the patient.

TREATMENT PROGRAMS

The ZYE XD® treatment program offers a treatment modality that encompasses the action of LASER at different depths and dimensions of the skin, promoting an improved aspect of the treated region regarding tone, quality, reduction of fine lines and wrinkles, blemishes, flushing and even flaccidity. This procedure does not generate downtime and restrictions on skin type and tanning

conditions are minimal if cautions mentioned in clinical literature are observed. The following are step-by-step instructions for performing the treatment:

1. Use DualMode® InLift® for intraoral region treatment, following the standard reference guide for the indication. The goal of treatment here is to promote a localized volumizing effect, as well as tightening and transient lifting effect;
2. ZYE YAG® should be used for the same purposes as thermal peeling – reduction of flushing, enlarged pores and fine lines and wrinkles. If you choose to treat any extra-facial area in this combination of treatment, you can also treat the cervical region (poikilodermia) with the 3 mm spot, following the recommendations in this clinical reference guide above. If you are using ZYE ALX®, you can combine the LongPulse® effect for this treatment step;
3. The collimated DualMode® spot, at 12 mm and with 200 us pulse time, seeks to promote a blemish homogenizing effect through a virtually non-ablative treatment that allows the combination of drug delivery through skin permeation.
    3.1. If the patient has many larger, localized spots or lesions, a viable option is to use DualMode® in single mode or ACROMA-QS. Remember, however, that this association may add some downtime to the treatment, given the LASER's effect on the tissue;
4. Treatment of the jowl contour, as a tightening effect of the LASER, and wrinkles and lines on the neck or chest may be an interesting option that adds important results to the treatment. The ZYE YAG® exclusive INTENSE® mode promotes such effect and adds safe and effective results.
5. Some of the treatments proposed herein may be performed with ETHEREA-MX® and available handpieces.

RED CARPET Achieve a glow and tightening effect with no downtime						
HANDPIECE	**SPOT**	**MODE**	**PULSE WIDTH**	**FLUENCE**	**REP. RATE**	**SHOTS**
DualMode®	InLift®	Fractional	-	30-40 mJ/mtz	0.5-1 Hz	100-150/ Side and 20-30/ Lip
3-10/VL 3-24/HR 5-15/LT	5 mm	DYNAMICS®	200-650 us	8-20 J/cm^2	5-10 Hz	500/ Quadrant
DualMode®	12 mm collimated	-	200 us	0.25 J/cm^2	10 Hz	1.000/ Quadrant
5-15/LT	10 or 15 mm	INTENSE®	15 s (time shot)	30-40 W	-	6 to 7 KJ/ Hemiface

GOLD Fine lines treatment and eyelids resurfacing, wit no downtime						
HANDPIECE	**SPOT**	**MODE**	**PULSE WIDTH**	**FLUENCE**	**REP. RATE**	**SHOTS**
DualMode®	InLift®	Fractional	-	30-40 mJ/mtz	0.5-1 Hz	100-150/ Side and 20-30/ Lip
3-10/VL 3-24/HR 5-15/LT	5 mm	DYNAMICS®	200-650 us	8-20 J/cm^2	5-10 Hz	500/ Quadrant
DualMode®	TrueLift® 8 mm	-	-	15-25 mJ/mtz	1 Hz	30-50/ Eyelid
DualMode®	12 mm collimated	-	200 us	0.25 J/cm^2	10 Hz	500 to 1000/ Quadrant

GLOW Achieve a glow effect and pore reduction, with no downtime						
HANDPIECE	**SPOT**	**MODE**	**PULSE WIDTH**	**FLUENCE**	**REP. RATE**	**SHOTS**
3-10/VL 3-24/HR 5-15/LT	5 mm	DYNAMICS®	650 us	10-20 J/cm^2	5-10 Hz	500 / Quadrant
ACROMA-QS®	7 mm	-	-	900-1200 mJ	5 Hz	6 to 8 passes/ Quadrant
DualMode®	12 mm collimated	-	200 us	0.25 J/cm^2	10 Hz	500 to 1000/ Quadrant

BLACK DRESS Treat grooves and fine lines with minimum downtime						
HANDPIECE	**SPOT**	**MODE**	**PULSE WIDTH**	**FLUENCE**	**REP. RATE**	**SHOTS**
DualMode®	InLift®	Fractional	-	30-40 mJ/mtz	0.5-1 Hz	100-150/ Side and 20-30/ Lip
ProDeep®	8/100 mtz	-	3 ms	90-100 mJ/mtz	1 Hz	Cover the whole area
DualMode® *+ Drug Delivery*	12 mm collimated	-	200 us	0.25 J/cm^2	10 Hz	500 to 1.000/ Quadrant

VELVET Reduce pore size, grooves and fine lines, with minimum downtime						
HANDPIECE	**SPOT**	**MODE**	**PULSE WIDTH**	**FLUENCE**	**REP. RATE**	**SHOTS**
3-10/VL 3-24/HR 5-15/LT	5 mm	DYNAMICS®	650 us	10-20 J/cm^2	5 -10 Hz	500/ Quadrant
ACROMA-QS®	7 mm	-	-	900-1200 mJ	5 Hz	6 to 8 passes
ProDeep®	8/100 mtz	-	3 ms	90-100 mJ/mtz	1 Hz	Cover the whole area

BEAUTY Skin Lightening and improved texture, with minimum downtime						
HANDPIECE	**SPOT**	**MODE**	**PULSE WIDTH**	**FLUENCE**	**REP. RATE**	**SHOTS**
3-10/VL 3-24/HR 5-15/LT	5 mm	DYNAMICS®	650 us	10-20 J/cm^2	5-10 Hz	500/ Quadrant
DualMode® *+ Drug Delivery*	8/400 mtz	Single Mode	300 us	2.0 mJ/mtz	3 Hz	Cover the whole area

SHINE Skin Lightening with minimum downtime						
HANDPIECE	**SPOT**	**MODE**	**PULSE WIDTH**	**FLUENCE**	**REP. RATE**	**SHOTS**
IPL-Sq®	540 or 580 nm	DYNAMICS®	10 ms	4-7 J/cm^2	3 Hz	Until endpoint
ACROMA-QS®	7 mm	-	-	900-1200 mJ	5 Hz	6 to 8 passes
DualMode® *+ Drug Delivery*	8/400 mtz	Single Mode	300 us	2-3 mJ/mtz	3 Hz	Cover the whole area

MAGNIFIC Achieve a glow effect and eyelid resurfacing, with no downtime						
HANDPIECE	**SPOT**	**MODE**	**PULSE WIDTH**	**FLUENCE**	**REP. RATE**	**SHOTS**
DualMode®	InLift®	Fractional	-	30-40 mJ/mtz	0.5-1 Hz	100-150/ Side and 20-30/ Lip
IPL-Sq®	695 nm	DYNAMICS®	10 ms	4-7 J/cm^2	3 Hz	Until endpoint
DualMode®	TrueLift®	-	-	15-25 mJ/mtz	-	30-50/ Eyelid
DualMode® *+ Drug Delivery*	12 mm collimated	-	200 us	0.25 J/cm^2	10 Hz	500 to 2.000/ Quadrant

All procedures may be associated with drug delivery; usually vitamin C is well accepted, but there are other active ingredients that may enhance response. Beware of acids in high concentrations, as they may increase downtime and favor hypercormia.

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9

SAMPLE CONSENT FORM

ZYE®

PATIENT DATA

Name		Gender	☐ M	☐ F
Id/SSN		Age		
Address				
City		State		
Legible Name				
Signature				

1. By this INFORMED CONSENT FORM, I HEREBY AUTHORIZE Dr. _____, a specialist in _____, as well as other professionals authorized and associated thereto, trained and able to use the equipment, to perform the **LASER treatment** procedure, using ZYE® LASER and handpieces technologies, which is the treatment that I have effectively contracted with this company for the following purpose(s) and the following area(s) of my body:

☐	☐	☐
☐	☐	☐
☐	☐	☐

described **treatment areas**:

_____

_____

_____

2. The technology used in the treatment proposed in Item 1 has been fully explained by the physician responsible for the application, in a prior appointment for guidance, in such a way that I understand the nature, characteristics, scope and respective limitations of the procedure. I was also clearly informed of all risks, consequences as well as any side effects and/or adverse effects resulting from the treatment in question. I, therefore, state that I am aware and in due agreement and that I assume all the possible risks and complications that may occur during the treatment, exempting the doctor and the clinic of any responsibility for any damages or losses, even if solely moral, that may occur. I have also been provided with a detailed explanation of the precautions I must follow during treatment to provide the desired result as well as to avoid undesired effects or side effects. I was given ample opportunity to clarify all my doubts, all of which were answered satisfactorily. The following aspects have been specifically clarified:
    a. the condition of the skin and its characteristics are relevant both at the time of indication and actual treatment. Thus, the information received was sufficient to support the decision to undergo treatment at the present time.
    b. I am aware that the results obtained may significantly vary among patients, fact related to the color and characteristics of the skin and treatment target condition, hormonal factors, genetic and even pathological features of the area or lesion to be treated.
    c. I have been properly examined, in a prior guidance appointment, and advised of treatment contraindications and I am fully aware that treatment should not

be performed in the event of any of the following conditions: undiagnosed open wounds; allergy to sunlight; use of anticoagulants; malignant lesions; pregnancy; anticoagulant drugs, diabetes and hormonal disorders, unless under control; history of keloid scars; history of coagulopathic hemorrhages; immunosuppressive diseases, vitiligo, eczema and psoriasis; and active infectious processes.

d. the procedure may result in: burning sensation in the area or lesion; formation of edema, erythema, petechiae and ecchymosis. In some cases, there is still a risk of infectious lesions.
e. I am aware that after each session, and at intervals, I must strictly follow all medical recommendations given to me.
f. treatment comprises several sessions, separated by an interval that may vary between 7 and 15 days, depending on the purpose, desired results and the individual assessment, in each case.

3. I am aware that the practice of medicine is not an exact science and I recognize that although I am clearly and adequately informed about the expected results of the procedure, specific outcomes cannot be assured. I understand that a same area may require several sessions to complete the treatment or achieve the expected results and, under this circumstance, I understood all the costs involved in the treatment. Such costs have been previously presented to me, to which I agree.
4. I undertake to immediately inform the aforementioned physician, or a physician appointed thereby, of any changes other than those previously explained.
5. I declare that I am not pregnant or suspecting pregnancy, a condition in which treatment should not be indicated. I further declare to be allergic to certain drugs and also to be undergoing treatment with the following medications:

I am allergic to the drugs listed below:

_____

_____

_____

I am currently undergoing treatment with the drugs listed below:

_____

_____

_____

6. I undertake to fully follow the guidelines, as failing to do so may endanger my health and well-being, causing temporary or permanent sequelae.
7. I undertake to attend all appointments before and after the procedure, having been clarified that the non-attendance may compromise the procedure and I further undertake to faithfully comply with all the provisions herein, as well as the medical advice previously provided.
8. I hereby declare that all information regarding the treatment has been provided and clarified, as set forth above, by the attending physician or those associated thereto, and I have clearly and accurately provided all the information requested.
9. I further confirm through this document that I am and should therefore be considered as an adult fully capable of making conscious and free-will decisions. I am over eighteen (18) years of age or, being a minor, I have been duly authorized by my legal guardian, who will also sign this document in the same manner as set forth in the following and previous items.
10. I declare to be aware that any side effects or unwanted effects, as well as any damages that I may suffer, can only be attributed to the applying physician, and also in the case of malpractice, imprudence or negligence, as well as in the absence of the duty to inform, according to the situations previously dealt with in this term, and of which I declare to be fully aware, exempting the manufacturer from any liability for damage suffered, even if solely moral.
11. I authorize the use of any photographs taken in the office, during the follow-up of treatment sessions (before and after), in which I freely and spontaneously expose my image for public and private use, provided that for clinical and/or educational purposes. Any use other than those indicated herein is strictly prohibited.
12. Finally, I declare that I have read this consent carefully and fully understood it, and that no further doubts remain. Thus, I authorize the performance of the aforementioned previously contracted procedure.

City, Month XX, XXXX

Signature

10

SAMPLE CONSENT FORM

ZYE®

PATIENT DATA

Name		Gender	☐ M	☐ F
Id/SSN		Age		
Address				
City		State		
Legible Name				
Signature				

1. By this INFORMED CONSENT FORM, I HEREBY AUTHORIZE Dr. _____, a specialist in _____, as well as other professionals authorized and associated thereto, trained and able to use the equipment, to perform the **intimate LASER treatment** procedure, using ZYE® ATHENA® LASER technology, which is the treatment that I have effectively contracted with this company for the following purpose(s) and the following area(s) of my body:

☐ dryness and irritation	☐ whitening	☐ aesthetics
☐ urinary incontinence	☐ vaginal flaccidity	☐

described **treatment areas**:

female intimate area (genital)

vulva, vagina and outer/inner lips

2. The technology specified to perform the treatment proposed in **Item 1** has been fully explained to me in an appointment for guidance, in such a way that I understand the nature, characteristics, scope and respective limitations of the procedure. I have been clearly informed of all risks and consequences, being aware of and agreeing to each and every risk and complication that may occur during treatment. I therefore undertake to exempt the doctor and clinic from liability for any damage that may occur, whether material or moral. I have been fully informed of all the precautions I must follow in order to avoid complications. I was given ample opportunity to clarify all my doubts, all of which were answered satisfactorily. The following aspects have been specifically clarified:
    a. the condition of the genital area and its characteristics are relevant both at the time of indication and actual treatment. Thus, the information received was sufficient to support the decision to undergo treatment at the present time.
    b. I am aware that the results obtained may significantly vary among patients, fact related to the condition of the epithelium in the treatment area, hormonal, genetic and drug factors, as well as anatomopathological characteristics of the area to be treated.
    c. I have been properly examined, in a prior guidance appointment, advised of treatment contraindications and I am fully aware that treatment should not be performed in the event of any of the following conditions: menstrual period, active herpes; undiagnosed open wounds; use of anticoagulants; malignant lesions; pregnancy; diabetes and hormonal disorders, unless under control; history of keloid scars; history of coagulopathic hemorrhages; immunosuppressive diseases; active infectious processes.

d. the procedure may result in: burning sensation in the area or lesion; edema and erythema formation; mild secretion and mild itching, hypopigmentation, or hyperpigmentation, depending on skin care and condition and pre- and post-treatment lesion; sensitivity of the treated area and eventual crust formation during the healing and tissue recovery process.
e. side effects may include change in skin color (hypopigmentation or hyperpigmentation). These changes are rare and usually temporary, but should be reported immediately in the event of any related occurrences.
f. I am aware that I should wear safety goggles throughout the treatment procedure to prevent eye damage from direct light emission to the eyes.
g. I am aware that after each session, and at intervals, I must strictly follow all medical recommendations given to me, including sexual abstinence for 7 days.
h. treatment comprises 3-4 sessions, separated by a treatment interval that may vary between 30 and 60 days, depending on the purpose, desired results and the individual assessment, in each case.

3. I am aware that the practice of medicine is not an exact science and I recognize that although I am clearly and adequately informed about the expected results of the procedure, specific outcomes cannot be assured. I understand that a same area may require several sessions to complete the treatment or achieve the expected results and, under this circumstance, I understood all the costs involved in the treatment. Such costs have been previously presented to me, to which I agree.
4. I undertake to immediately inform the aforementioned physician, or a physician appointed thereby, of any changes other than those previously explained.
5. I declare that I am not pregnant or suspecting pregnancy, a condition in which treatment should not be indicated. I further declare to be allergic to certain drugs and also to be undergoing treatment with the following medications:

I am allergic to the drugs listed below:

_____

_____

_____

I am currently undergoing treatment with the drugs listed below:

_____

_____

_____

6. I undertake to fully follow the guidelines, as failing to do so may endanger my health and well-being, causing temporary or permanent sequelae.
7. I undertake to attend all appointments before and after the procedure, having been clarified that the non-attendance may compromise the procedure and I further undertake to faithfully comply with all the provisions herein, as well as the medical advice previously provided.
8. I hereby declare that all information regarding the treatment has been provided and clarified, as set forth above, by the attending physician or those associated thereto, and I have clearly and accurately provided all the information requested.
9. I further confirm through this document that I am and should therefore be considered as an adult fully capable of making conscious and free-will decisions. I am over eighteen (18) years of age or, being a minor, I have been duly authorized by my legal guardian, who will also sign this document in the same manner as set forth in the following and previous items.
10. I declare to be aware that any side effects or unwanted effects, as well as any damages that I may suffer, can only be attributed to the applying physician, and also in the case of malpractice, imprudence or negligence, as well as in the absence of the duty to inform, according to the situations previously dealt with in this term, and of which I declare to be fully aware, exempting the manufacturer from any liability for damage suffered, even if solely moral.
11. I authorize the use of any photographs taken in the office, during the follow-up of treatment sessions (before and after), in which I freely and spontaneously expose my image for public and private use, provided that for clinical and/or educational purposes. Any use other than those indicated herein is strictly prohibited.
12. Finally, I declare that I have read this consent carefully and fully understood it, and that no further doubts remain. Thus, I authorize the performance of the aforementioned previously contracted procedure.

City, Month XX, XXXX

Signature

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SAMPLE GUIDELINES FOR PATIENTS

ZYE®

The information provided on this form encompasses most medical-aesthetic procedures using LASER, including LASER hair removal, skin whitening, vein and vessel treatment and skin tightening and flaccidity.

POTENTIAL SIDE EFFECTS

- The best way to minimize the risk of side effects is to avoid sun exposure for 7 days before and after treatment;
- Talk to your physician and provide him/her with your most accurate and up-to-date health data for a safe and effective treatment;
- Side effects are temporary and uncommon but may include hyperpigmentation (darkening of the skin), hypopigmentation (loss of skin pigmentation), mild or moderate burns (even blistering), temporary/transient redness, follicular edema (for hair removal), swelling and itching in the treated area, bruising and even lack of desired results;
- Pregnant patients should be aware that hormonal changes may significantly affect the effectiveness of LASER treatments;

GENERAL GUIDELINES PRIOR TO TREATMENT

- Avoid all products containing alphahydroxy and betahydroxy (AHA/BHA), hydroquinone, retinols/retinoids, aspirin, Tazorac, Differin and Vitamin E for 3 days prior to treatment;
- Patient skin in the area to be treated should be clean (free of makeup) at the time of the procedure;
- Avoid prolonged sun exposure or tanning for up to one week before starting treatment (or treatment sessions);
- Sunburned or sunburned patients should wait at least 2 weeks for the procedure to avoid additional skin damage. Also avoid applying self-tanning lotions for 3 days before treatment;
- For LASER or light hair removal, the area to be treated should be well shaved (do not use tweezers and do not wax or use other depilatory creams that may remove the hair structure completely or at the root). It is recommended that any hair removal procedures be avoided for up to 3 weeks before treatment;
- If you are prone to fever blisters, take a doctor-prescribed antiviral medication before starting treatment or follow the prescribed medical guidelines;
- Patients who have used isotretinoin (Roaccutane®) for the past 6 months CANNOT perform the LASER skin resurfacing procedure (tissue peeling and cell renewal);
- Patients should not engage in any physical activity that increases body temperature or blood pressure immediately before or after LASER treatment;
- If you are prone to histamine (allergic) reactions, inform your physician before receiving any LASER treatment;

GUIDELINES: **LASER HAIR REMOVAL**

- Patients with red, gray or blond hair in the area to be treated should consult the doctor before receiving treatment, since LASER will be less effective on those shades;
- During treatment you may experience slight discomfort, similar to a clicking sensation. Topical anesthetic agents are available by prescription (at medical discretion) and may be applied 60 minutes before treatment;
- You should notice slight redness and swelling in the treated area for up to 72 hours after the procedure. If such conditions persist, topical creams or soothing solutions may be applied and prescribed for home use;
- Wait at least 1 week after treatment for the hair to fall out naturally;
- On average, patients report a 20-30% decrease in hair growth rate after each session. This number increases to 70-90% after 8 to 12 treatment sessions;
- For best results, keep a consistent treatment schedule with your physician.

GUIDELINES: **VEIN AND VESSEL TREATMENT**

- Patients on high doses of anticoagulants or aspirin should not receive this treatment. Talk to your physician and provide a detailed history of your health condition;
- Patients with problems related to poor circulation (diabetics) or using small doses of anticoagulants or aspirin may experience increased post-treatment bruising and delay in the overall healing process;
- Discontinue the use of anticoagulants or aspirin one week before and after treatment if approved and/or recommended by your physician (at the physician's sole discretion);

- Veins and vessels will change from a purplish to reddish color after treatment; blood leakage and bruising also may occur and last 2-6 weeks;
- Avoid extreme physical activity for up to 48 hours after treatment to ensure the best result. For treatment areas larger than 10 x 10 cm, keep the region in an elevated position for about 4-6 hours after the treatment session ends;
- Schedule a follow-up appointment 6 weeks after treatment as recommended by the attending physician;
- To achieve an optimal outcome, most patients require 2 to 3 treatment sessions, scheduled 6 to 8 weeks apart;

GUIDELINES: **SKIN WHITENING**

- During treatment, the pigmented areas will turn to gray, acquire a reddish appearance and then gradually disappear. Within 2 to 3 days following treatment, the pigmented areas will become about 3x darker than the original color;
- The pigment will create a crust and begin to peel within 5 to 7 days. IMPORTANT: Never remove crusts as this will cause hypopigmentation and scarring;
- Most patients require 2 to 3 treatment sessions to achieve the best results. Thus, schedule the treatment with some regularity, according to medical recommendation;
- As recommended by a physician, the regular exfoliation process and home use of a skin whitener are highly recommended to maintain results;

GUIDELINES: **SKIN TIGHTENING AND FLACCIDITY**

- This treatment is ideal for flaccid skin in the neck, chest, arms and abdomen;
- During the procedure, the treated area will become much warmer and soft;
- You may experience intense redness, increased sensitivity and residual swelling for up to 48 hours after the treatment session;
- For the best results, it is recommended that 6 to 12 treatment sessions be conducted at regular treatment intervals of 1 to 2 weeks;

GUIDELINES: **LASER TREATMENT FOR INTIMATE AREAS**

- In the post-procedure period, you may experience mild discomfort and a warming sensation within the vaginal canal. In treatments performed on the outer region of the labia and groin, there may also be slight peeling and itching due to the healing process;
- You may also experience mild secretion in the first days following treatment;
- The symptoms described above should disappear within 3 days. In case of doubt, consult the physician on what to do;
- Avoid sexual intercourse for at least 7 days after the procedure;
- Further treatment sessions are recommended every 90 or 120 days, depending on the degree of indication.

CARE AFTER TREATMENT

- Avoid prolonged sun exposure or tanning during the week following treatment;
- If blisters emerge, do not puncture them. If the skin is dry, apply antibiotic ointment until the healing process is complete. Do not scratch any lesions, as this will increase the risk of side effects;

- In case of post-treatment discomfort, some topical or oral medication may be prescribed for relief (at medical discretion). You can apply cold towels, ice packs, aloe vera or chamomile to ease the discomfort caused by the heat;
- Avoid additional LASER treatments or chemical procedures in the treated area for at least 2 weeks after the treatment session or until complete healing;
- Use of a broad spectrum UVA/UVB SPF 30 is critical when receiving LASER treatments and is recommended for maintaining the results obtained;

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SAMPLE TREATMENT RECORD

ZYE®

This form is a physician-only form as indicated in the **Informed Consent Form**. The repetition of the data included herein is necessary for the registering and filing of patient charts, respecting the legal requirements for each case, in different clinical practices, specialties and types of structure.

	Patient Code

Patient Name		**Age**	

Date				
	Day	Month	Year	No. of Visits and Treatment Interval

WERE POST-TREATMENT GUIDELINES PROVIDED TO THE PATIENT?	☐ Y	☐ N

Pictures	☐ Y	☐ N

Before	After

1 Treatment Goals

☐ *Other*
☐ *Other*
☐ *Other*
☐ *Other*
☐ *Other*
☐ *Other*
☐ *Other*

2 Treatment Plan

3 Treatment association

4 Return History

Visit #		Interval		Date		Improvements	☐ Y	☐ N
Comments								

Visit #		Interval		Date		Improvements	☐ Y	☐ N
Comments								

Visit #		Interval		Date		Improvements	☐ Y	☐ N
Comments								

Visit #		Interval		Date		Improvements	☐ Y	☐ N
Comments								

Visit #		Interval		Date		Improvements	☐ Y	☐ N
Comments								

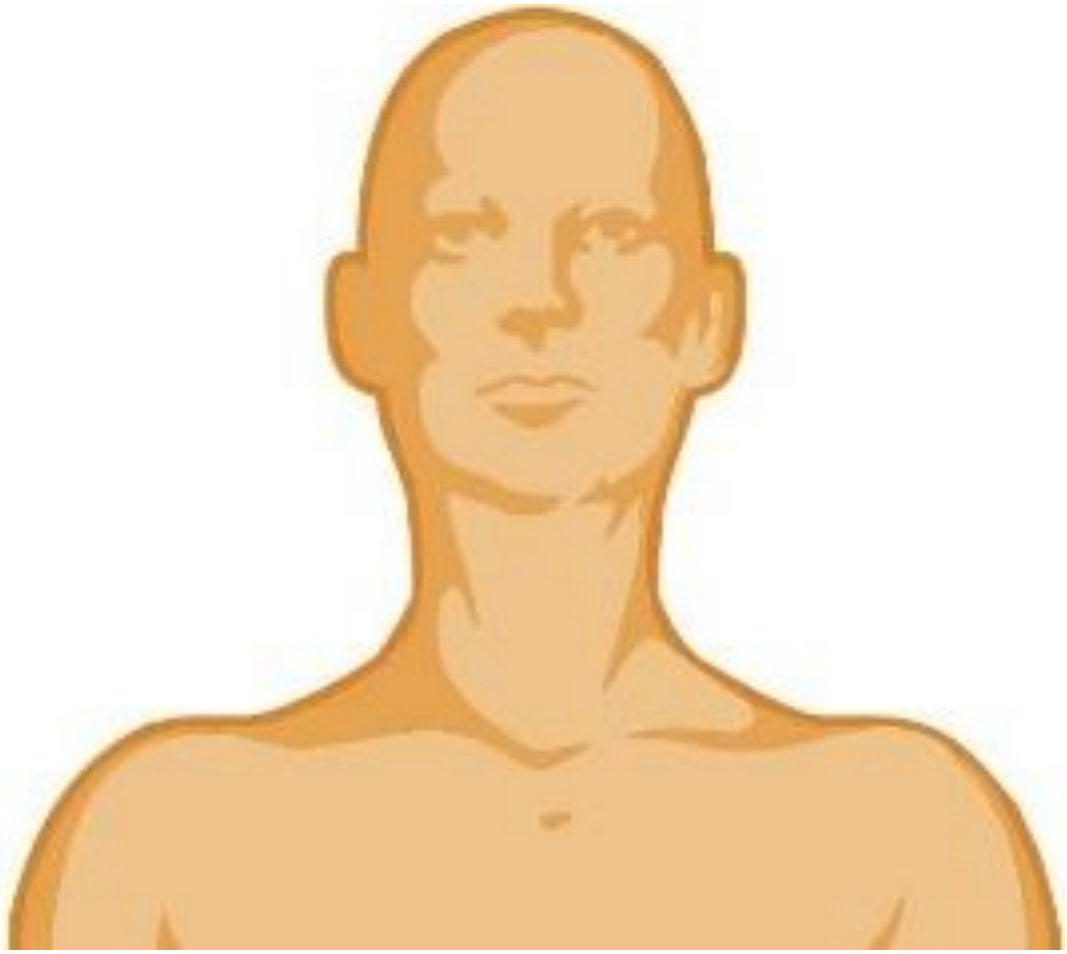
Visit #		Interval		Date		Improvements	☐ Y	☐ N
Comments								

Visit #		Interval		Date		Improvements	☐ Y	☐ N
Comments								

Visit #		Interval		Date		Improvements	☐ Y	☐ N
Comments								

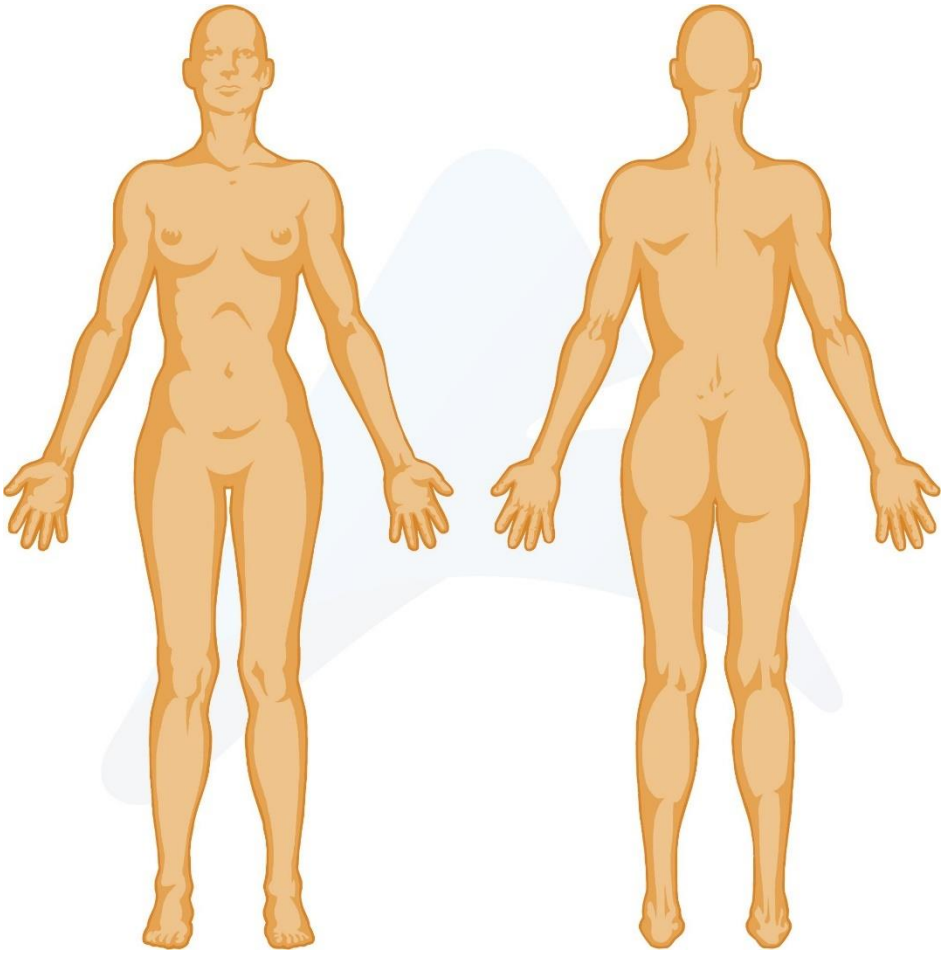
Visit #		Interval		Date		Improvements	☐ Y	☐ N
Comments								

TREATMENT PARAMETERIZATION



TREATMENT AREAS INDICATED IN THE IMAGE

TREATMENT PARAMETERIZATION



TREATMENT AREAS INDICATED IN THE IMAGE

5 Notes

6

Treatment Area		Session	

ZYE® Parameters	
ZYE® Parameters	
Notes	

I certify, for all intents and purposes, the truthfulness and origin of informations herein.

Doctor's Name	
Signature	
Stamp	

Date	

Preparation	Review	Approval
Clarissa Bravin	Antonio Olivatto	Eduardo Nico
Giovana Milani		
Renata Novais		

Review	Date	Description	Person in charge
1.0	07/17/2019	Document issuance	Antonio Olivatto
1.1	09/02/2019	Inclusion of indications	Giovana Milani
1.2	11/09/2020	General Review	Clarissa Bravin